

### REMARKS/ARGUMENTS

This is in response to the Office Action mailed July 13, 2004. Currently pending are claims 21-27, 29 and 35-77. Claims 21-27, 29, 35-37 and 56 are amended and claims 69-77 are withdrawn.

In the Action, claims 21-27, 29 and 35-77 were subject to a restriction and election requirement. The Applicants appreciate the telephone discussion of July 3, 2004 with the Examiner to clarify the Examiner's action. To assist with responding to the Examiner's restriction requirement, the Applicants are categorizing the restriction/election into Groups I, II and III and their respective subgroups.

The Examiner has required the Applicants to elect one of three groups: Group I consisting of claims 21-27, 29 and 35-37, relating to a method of treating obesity, Group II, consisting of claims 38-68, relating to a method of regulating body weight, or Group III, consisting of claims 69-77, relating to a method of identifying an antagonist.

Furthermore, the Examiner has required the Applicants to elect from various subgroups.

The Examiner sets forth a general election requirement, with claims 39 and 42 as examples. According to the Examiner, the Applicants are required to choose one species from one of the following subgroups:

- Subgroup (A): a 1,25-(OH)<sub>2</sub>-D receptor antagonist, of which Applicants must elect either (1) an antibody or (2) a chemical compound; or
- Subgroup (B): a 1,25-(OH)<sub>2</sub>-D antagonist, of which Applicants must elect one of the following: (1) an antibody, (2) a chemical compound, (3) one or more soluble 1,25-(OH)<sub>2</sub>-D receptors, (4) 1,25-(OH)<sub>2</sub>-D neutralizing antibodies, (5) soluble 1,25-(OH)<sub>2</sub>-D receptor, (6) fusion proteins comprising the 1,25-(OH)<sub>2</sub>-D receptor, (7) compounds comprising calcium, or (8) calcium.

The Examiner further requires that if Applicants elect Group II, then the following elections of species are required:

- Subgroup (C): one of the species of claim 55 relating to calcitrophic hormone activity, which include (1) inhibiting lipolysis, (2) stimulating lipogenesis, (3) increasing adiposity, (4) stimulating triglyceride accumulation, (5) increasing intracellular calcium concentration ( $[Ca^{2+}]_i$ ), (6) inhibiting adipocyte uncoupling protein 2 (UCP2) expression or stimulating fatty acid synthase (FAS) activity;
- Subgroup (D): one of the species of claim 56 relating to health problems, which include (1) coronary artery disease, (2) stroke, (3) diabetes, (4) osteoarthritis, (5) ligament injuries, (6) perineal dermatitis, (7) diabetes mellitus, (8) cardiomyopathy or (9) urologic syndrome; and
- Subgroup (E): one of the species of claim 61 relating to the activity of the antagonist, which includes (1) suppresses adiposity, (2) inhibits triglyceride accumulation, (3) reduces intracellular calcium concentration ( $[Ca^{2+}]_i$ ), (4) increases adipocyte uncoupling protein 2 (UCP2) expression, (5) increases core temperature, (6) accelerates weight loss and fat mass reduction in an individual under caloric restriction or (7) prevents stimulation of fatty acid synthase (FAS) activity.

The Examiner also states that if the Applicants elect Group III, then the Applicants must elect from one of the species listed in claim 70. During the telephone discussion of July 3, 2004, the Examiner asked the Applicant to cross out claim 71 from the on top of page 5 of the office action.

In response to the restriction/election requirement, the Applicants elect Group II, claims 38-69 and currently amended claims 21-27, 29 and 35-37, with the further election of subgroup A, 2, relating to a chemical compound 1,25-(OH)<sub>2</sub>-D receptor antagonist, subgroup C, 5, wherein the inhibited calcitrophic activity is increased intracellular calcium concentration ( $[Ca^{2+}]_i$ ), subgroup D, 1, relating to coronary artery disease, and subgroup E, 3, relating to reducing intracellular calcium concentration ( $[Ca^{2+}]_i$ ). The elected matter includes claims 21-24, 35-41 and 50-68. Non-elected matter includes claims 25-27, 29 and 42-49. Claims 69-77 have been cancelled. Should the examiner find the elected species patentable, it is then respectfully

requested that the non-elected species be examined. The Applicants reserve the right to file a divisional application to all claims withdrawn, cancelled or restricted out. The Applicants elect these embodiments with traverse.

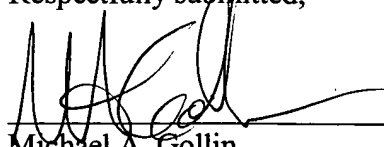
Applicants submit that the restriction requirement is improper and should be withdrawn because the Examiner has not met the burden of proving that the referenced groups and subgroups are distinct and separate and will place a serious burden on the Examiner. MPEP 1504.05 and 803(A) and (B). The Examiner is required to show by appropriate explanation that there will be a serious burden on the Examiner to search the related art because of a separate classification, a separate status in the art, or a different field search as defined in MPEP 808.02. The Examiner has not done so, therefore the Applicants respectfully request that the restriction requirement be withdrawn and the claims be examined.

Furthermore, if the members of a Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they may be directed to independent and distinct inventions. MPEP 803.02.

The Applicants contend that embodiments listed in claims 39 and 42 are sufficiently few and are closely related that a search and examination of the entire claims would not be a serious burden on the examiner. Claims 21-27, 29, 35-37 and 56 have been amended, which should obviate the Examiner's rejection. Moreover, the activities listed in claims 55 and 61 are effects produced by using the antagonist of the present invention. Each effect would not have to be searched but instead only the antagonist would be searched and therefore, there is no burden on the Examiner to continue prosecution of these claims.

The Examiner is invited to call the undersigned, should any minor issues remain to place the case in condition for allowance.

Respectfully submitted,



Date: September 10, 2004

Michael A. Gollin

Registration No. 31,957

Zayd Alathari

Registration No. 42,256

VENABLE

P.O. Box 34385

Washington, D.C. 20043-9998

Telephone: (202) 344-4000

Telefax : (202) 344-8300

MAG:ZA  
DC2#568559